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FDA REGULATION AND THE NEW ANTI-AGING PRODUCTS

I. INTRODUCTION

In the decades since the enactment of the Federal Food, Drug, and Cosmetic Act (the **Act**)¹ in 1938, one of the more persistent challenges facing the Food and Drug Administration (the FDA) has been to apply an old statute to the regulatory problems generated by new technologies. The development of new anti-aging skin preparations is a recent example of this phenomenon. Although potions purporting to make the skin younger have existed for centuries, today's youth-seekers are spending billions on new products that just might work.² In particular, the development of alpha hydroxy acids (AHAs) has been promising.³ Derived from fruit, sugar cane, and milk, AHAs cause the surface layer of dead skin cells to shed, hastening the appearance of fresh cells. The laboratory results are inconclusive thus far, but preliminary research shows that some products may deliver active ingredients to the skin's inner layer, stimulating the production of moisturizing acids and cells such as collagen that help to keep the skin firm.⁴

The ability of AHAs to penetrate the skin and alter cell structure raises an important question: does the Act adequately protect consumers from cosmetics that may work so well as to change the way the body operates? Currently, even if a skin cream behaves like a drug by affecting the structure or any function of the body, it will generally be considered a

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cosmetic under the Act if the manufacturer refrains claiming that the AHA product works like a drug. Products classified as cosmetics under the Act are relatively unregulated; the Act does not subject them to most of the restrictions imposed upon drugs -

- including mandatory registration, premarket safety and effectiveness testing, premarket FDA approval, and postmarket surveillance to monitor safety.

This paper will address whether the current regulatory environment is adequate to protect consumers both from the economic injuries that may arise from misleading claims made by AHA manufacturers and from the physical injuries that may arise from the use of AHAs. Part II describes the current regulatory environment applicable to AHA products and assesses the FDA's ability to protect consumers from deception and physical injury. Balancing the health, safety, and economic benefits of increased regulation against its costs to the FDA, to business, and to consumers, part III analyzes the adequacy of this regulatory environment and concludes that consumers are sufficiently protected and that the FDA's human and financial resources should be expended on more pressing concerns.

II. REGULATING ANTI-AGING PRODUCTS UNDER THE ACT

AHA products threaten consumers in two ways. First, they may cause economic injuries by misleading consumers into believing that AHAs are a guaranteed miracle cure for wrinkles. In fact, scientists have not progressed beyond speculation as to

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how AHAs work and whether they really fight wrinkles. Second, AHAs may cause both short-term and long-term physical injuries to consumers. Temporary rashes and skin irritations have appeared in some AHA users. Moreover, if AHAs actually penetrate the skin and cause increased cell turnover, scientists fear that dizziness, headaches, or shortness of breath could result,⁶ that new cells might be abnormal, or that the acceleration of skin cell exfoliation might reduce the skin's natural protection against the elements.⁷ Like the potential effectiveness of AliAs, most of these potential dangers are also speculative.

Currently, the FDA may employ three strategies to protect consumers from both economic and physical injuries caused by AHA products. First, the FDA can threaten to classify an AHA product as a drug if the manufacturer represents that it works like a drug. This enforcement strategy protects consumers from a wrinkle cream's misleading claims, because the manufacturer would rather refrain from making such claims than to have the FDA call its product an unapproved new drug and force it from the market.⁸ If the manufacturer does not make drug claims, the FDA can protect consumers by enforcing the adulteration or misbranding provisions of the Act.⁹ The adulteration provision protects consumers against cosmetics that contain any poisonous or deleterious substance which may render it injurious to users. If research shows AliAs to be dangerous, then the FDA can prohibit or restrict the use of AliAs in cosmetic products. The

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misbranding provision protects consumers from economic injuries by prohibiting cosmetic labeling that is false or misleading in any particular, and it protects against physical injuries by requiring conspicuous labeling of the manufacturer's name, place of business, the product's ingredients, and, in some cases, warnings about the product.

A. Classification of AHAs as Drugs

The FDA's main line of attack against wrinkle creams has been to argue that manufacturers' representations about how the products work render the products drugs under the Act. Classifying a cosmetic product as a drug and threatening the manufacturer with seizure actions is an effective strategy to protect consumers against economic injuries. Because of the enormous costs of the drug approval process, cosmetic companies have a strong incentive to keep an AHA product classified as a cosmetic. Thus, manufacturers will refrain from the most outrageous unproven claims about AHAs, such as Avon's claims that its Momentum cream accelerates normal cell renewal rate . helps fresh new skin cells surface faster ... ~h]elps prevent lines and wrinkles ... [w]orks beneath skin's surface to help prevent cell destruction ... and help us] maintain the integrity of fresh, new cells.¹⁰ Because of the FDA's threats, consumers are less likely to be deceived into thinking that the products do more than merely enhance the appearance. **11**

Under the Act, an anti-aging product may be classified

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either as a drug or as a cosmetic, or as both, depending not on the product's inherent properties, but rather on the product's intended use.¹² Under the Act, cosmetics are intended to be rubbed, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance

,~ while drugs are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease

- .. [or] intended to affect the structure or any function of the body ~ In distinguishing drugs from cosmetics, the FDA has focused on the latter part of the drug definition -i.e., whether a product is intended to affect the structure of the body.

Because even water, when applied to the skin, temporarily changes the skin's structure, the FDA and the courts have distinguished drugs from cosmetics by focusing on a product's intended use, which can be determined by examining the labeling, advertising, and other circumstances surrounding the manufacturer's representations about the product.¹⁵ This intended use doctrine means that a product utterly lacking of drug characteristics nevertheless will be classified as a drug if the manufacturer claims that the product acts like a drug.¹⁶ Conversely, cosmetic products that may behave like drugs will generally be classified as cosmetics, provided that the manufacturer makes no drug claims about the product.¹⁷ Thus,

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the inclusion of biologically active agents does not in itself make a cosmetic product a drug: a product is a drug only if a manufacturer makes drug claims about it or if a product contains substances in concentrations known actually to affect the structure of the body.⁸

In the late 1960s, before AliAs appeared, the FDA sought to classify cosmetics that claimed to smooth, reduce, or prevent wrinkles as drugs. Classifying the cosmetic product as a drug allowed the FDA to seize it, because a drug cannot be sold until FDA approval or until the manufacturer demonstrates that it is generally recognized as safe and effective by qualified experts.⁹

In the three published seizure actions instituted by the FDA against wrinkle creams, the FDA was successful in two cases. In United States v. An Article ... Sudden Change,²⁰ the Second Circuit upheld the FDA's position, that (r)egardless of the actual physical effect of a product, it will be deemed a drug for purposes of the Act where the labeling and promotional claims show intended uses that bring it within the drug definition.²¹ Applying the ignorant, the unthinking, and the credulous²² consumer standard rather than a reasonable woman standard, the court analyzed Sudden Change's claims that the product would lift out puffs and give a face lift without surgery. The court concluded that these claims would lead an ignorant, unthinking, or credulous person to believe that the product was

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intended to act as a drug by affecting the body's structure.²³ The Third Circuit reached a similar result in United States

v. An Article ... Line Away,²⁴ because the manufacturer's promotional materials contained strong therapeutic implications that exceeded the bounds of mere puffery.²⁵ Specifically, the manufacturer boasted that the product was made in a pharmaceutical laboratory and that the product was 'super active' and 'amazing,' creating a 'tingling sensation' when 'at work', 'tightening' the skin and 'discouraging new wrinkles from forming.' „²⁶

In United States v. An Article ... Helene Curtis Magic Secret ...,²⁷ however, the Maryland federal district court rejected the FDA's attempt to classify a wrinkle cream as a drug. Finding Magic Secret's claim that it was a 'pure protein' which causes an 'astringent sensation' to be less exaggerated than those reported in Line Away and Sudden Change, the court concluded that even the 'ignorant, unthinking and credulous' consumer would be capable of recognizing that the product could do no more than to alter the appearance. **28**

Armed with the principles established by these precedents and faced with an array of new cosmetic products, the FDA in the late 1980s resumed its attack on products accompanied by physiological claims about fighting the aging process. In 1987, the FDA dispatched regulatory letters to more than twenty cosmetic companies, informing them that certain claims would

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render their products new drugs marketed without an approved new drug application and requesting – under the threat of seizures or injunctions – correction of the violations.²⁹ In response to some of the companies' objections and questions, the FDA wrote a letter in November 1987 to articulate the difference between drug claims and cosmetic claims. According to the FDA, any claim that a product will affect the body – even temporarily – in a physiological way will constitute a drug claim. Specifically,

claims that a product counteracts, retards, or controls aging or the aging process, as well as claims that a product will rejuvenate, repair, or renew the skin are drug claims [A]lso, all of the examples

[that] allege an effect within the epidermis as the basis for a temporary beneficial effect on wrinkles, lines, or fine lines are unacceptable. A claim such as molecules absorb ... and expand, exerting upward pressure to 'lift' wrinkles upward is a claim for inner, structural change.³⁰

The FDA described acceptable claims for cosmetic products as relating to a physical (as opposed to a physiological) effect on the appearance or the feel of the skin. Therefore, a skin cream would remain a cosmetic if it claims to

temporarily improve the appearance of ... outward signs of aging ... , to cover up the signs of aging, to improve the appearance by adding color or luster to the skin, or otherwise to affect the appearance by physical means. . [A] product that claims to improve or maintain temporarily the appearance or the feel of the skin ... , [or] a product that claims to moisturize or soften the skin is a cosmetic

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The FDA's regulatory letters prompted most of the companies to refrain from making drug claims, advancing the FDA's goal of protecting consumers from deceptive marketing. Other manufacturers, however, continue to market their products with

drug-like claims – probably with the expectation that the FDA does not place a high priority on regulating cosmetics.³² Thus, the FDA’s strategy of threatening to classify as drugs those cosmetic products that claim to affect the skin’s physiology is at least somewhat effective against the threat of economic harm to consumers. In addition, consumer safety is relatively unprotected by the classification strategy, because a product can generally avoid being classified a drug so long as the manufacturer refrains from any drug claims and so long as the physiological effect of AliAs on the skin’s structure remains unknown.

B. Regulation of AliAs Under the Adulteration Provision.

Provided that an AHA manufacturer claims that its product enhances the appearance by physical but not physiological effect,³³ a cosmetic generally may contain biologically active agents without becoming a drug.³⁴ In other words, a cosmetic may actually affect the structure of the body so long as the manufacturer does not represent that it does so. This does not mean, however, that cosmetics are free to include whatever substances they choose – the Act protects consumer safety by authorizing FDA action against adulterated cosmetics. „36

A cosmetic is deemed adulterated if it contains a substance that may make the product injurious to users when used according to the label or in its customary fashion.

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Unfortunately, protecting consumers from injuries that may arise from cosmetics under this provision is difficult. Court-action against an allegedly unsafe cosmetic requires the FDA to meet a high burden of proving injury, and rule-making is slow.³⁸ Cosmetic companies are not required to register their plants or products, to file data on the ingredients in their products, to file reports of cosmetic-related injuries, nor to test their products for safety.³⁹ Even if the FDA requests safety information, a cosmetic company can refuse to provide it. Under the current voluntary reporting system, as of 1990, fewer than 40 percent of cosmetics manufacturers had registered their plants with the FDA, and only about 3 percent of cosmetics distributors had filed any injury reports.⁴⁰ Because of limited resources, the relative safety of cosmetics, and industry self-regulation, the FDA has not conducted independent investigations on very many cosmetic products. Instead, the FDA decides which cosmetics to investigate by relying on the consumer complaints it receives directly and on the scientific literature.⁴¹ With respect to AliAs in particular, the FDA has adopted a wait-and-see posture because of the extremely few consumer complaints it has received about AliAs.⁴² The FDA plans to reassess this policy when further research develops, including a report on AHAs that the Cosmetics Ingredient Review Board will release later in 1995.~~

C. Regulation of AHAs Under the Misbranding Provision.

Another way for the FDA to protect consumers against both

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economic and physical injuries arising from AliAs is to enforce the Act's provisions regarding misbranded cosmetics.⁴⁴ Consumer economic injuries can be prevented by prohibiting manufacturers from using labeling that is false or misleading in any particular.⁴⁵ Consumer physical safety can be enhanced by requiring warning labels or by seizing (or threatening seizure of) AHA products that lack warning labels, if the FDA can show that AHAs present a substantial risk of injury or illness from any handling or use that is customary or usual.⁴⁶

Currently, manufacturers must label cosmetics with a list of ingredients in descending order of predominance, with the exception of flavors and fragrances.⁴⁷ This regulation does little to help consumers distinguish products with varying concentrations of AliAs, making it difficult for consumers to know how powerful a product might be.⁴⁸ A misbranding regulation also requires cosmetics that have not been adequately substantiated for safety prior to marketing to contain a warning to that effect.⁴⁹ This provision is difficult to enforce, however, because the FDA lacks authority to require safety testing and injury reporting - - making it difficult for the FDA to argue that safety has not been adequately substantiated.

III. ANALYSIS AND CONCLUSIONS

Despite the limits on the FDA's ability to regulate cosmetics in an age when cosmetics increasingly are taking on the attributes of drugs, the social costs of increased FDA regulation

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far outweigh the safety and economic benefits. Advocates of increased FDA regulation of cosmetics have advanced two primary concerns: protecting consumers from unsafe products and protecting consumers from deceptive practices. Both of these goals are substantially satisfied under the current system; regulating cosmetics more strictly would increase the benefits only marginally. When these marginal benefits are weighed against the costs of increased regulation, including the diversion of FDA resources from more important public health issues, the arguments for increased regulation fail.

In light of recent developments in cosmetics technology, consumer advocates argue that it is time to reassess the efficacy of a regulatory regime constructed over fifty years ago. Powerful new products like AliAs are reaching the market with no proof of safety, possibly endangering consumers with unknown side effects. Also, clever marketing has lured consumers to spend billions of dollars on products that have not demonstrated that they actually do anything. Consumer advocates, therefore, have proposed to amend the Act in order to give the FDA more authority over cosmetics. Legislative proposals include the creation of a new cosmeceutical category, consisting of cosmetics with drug characteristics. Any so-called cosmeceutical would be required to seek premarket approval and to undergo safety testing.⁵⁰ Other proposals would increase the regulation of all cosmetics by requiring manufacturers to register with the FDA, keep adequate

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safety data, and file injury reports.⁵⁷ Others simply argue that the FDA should increase its policing of the cosmetics industry under existing laws.

Increased regulation would not prevent a significant number of economic injuries. The misbranded cosmetics provision of the Act already prohibits deceptive cosmetic labels, and the FDA prevents outrageous physiological claims about cosmetics by threatening to classify the offending cosmetics as drugs. The FDA's ability to protect consumers against economic injury is supplemented by the Federal Trade Commission's authority over advertising, as well as by modern consumers' ability to take cosmetic puffery with a grain of salt. Increased regulation, however, would give the FDA more information about products and manufacturers, enabling the FDA to enforce the misbranding provision more effectively. Additionally, requiring cosmeceuticals to meet the same standards as drugs would entail premarket proof of efficacy – forcing products that do not work from the market and preventing consumers from wasting money on useless products.

Although protecting consumers from deceptive practices is important, the FDA's primary role is to guard public health and safety. Accordingly, the most forceful argument for any proposal to increase the regulation of cosmetics is that physical injuries might be prevented. Premarket safety testing and FDA approval for cosmeceuticals would obviously decrease the risk of injury

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from AliAs by keeping them off of the market, perhaps permanently. The milder proposal – requiring registration of cosmetics manufacturers with the FDA and disclosure of safety data and injury reports – would bolster the FDA’s ability to gather information about cosmetic products. The FDA could use this information to keep an eye on fly-by-night manufacturers, to seize cosmetics that are injurious to users, or to publicize warnings about bad manufacturers and products.

Despite the enhanced safety that would accompany increased regulation, the current system adequately, if not perfectly, protects consumer safety. On the whole, cosmetics are safe products that have caused remarkably few serious injuries. Whether the FDA threatens to classify a cosmetic as a drug or chooses to enforce the adulterated cosmetics provision of the Act, the FDA is capable of addressing the most serious hazards posed by cosmetics. Thus, premarket FDA approval would probably bring only minimal additional safety. In other words, increased regulation might prevent a few temporary rashes, but it is unlikely to prevent any serious harms or deaths. Moreover, voluntary registration and industry self-regulation work fairly well. A large majority of cosmetics on the market are produced by large manufacturers who voluntarily register with the FDA and file injury reports.⁵² Also under the aegis of self-regulation, harmful ingredients have been removed from the market. In fact, the Cosmetics Ingredient Review Board is currently reviewing the

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safety of AliAs.

Even if one is persuaded that increased regulation would substantially improve the FDA's ability to protect consumers, the costs of increased regulation are unreasonable. Increased regulation would impose substantial costs on the cosmetics industry, many of which would necessarily be externalized to consumers. Requiring premarket safety testing and FDA approval of cosmetics, for example, would take years and cost millions of dollars. These costs, as well as the costs of decreased competition resulting from products exiting the market, would necessarily pass to consumers. In the years prior to approval, regulation would deprive consumers of the ability to purchase AHA products altogether. If approval ever comes, AHA products would be significantly and perhaps prohibitively more expensive. In a free market, consumers would probably prefer cheaper products available now than more expensive (and probably not much safer) products available later. Efficient regulation should match what consumers would be willing to pay for, and few would willingly spend so much for such marginal potential increases in safety.

Mandatory registration and safety/injury disclosure to the FDA, however, would not unduly burden the cosmetics industry and the consumer. Providing the FDA with more information would increase the agency's ability to enforce the laws against drug claims, misbranding, and adulteration. Nevertheless, requiring the FDA to use this information to regulate cosmetics more

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stringently or, more importantly, requiring the FDA to approve cosmeceuticals prior to marketing, imposes an unreasonable burden on the government's resources.

As an agency with limited resources, the FDA cannot attack all public health problems with equal vigor. Rather, it must allocate its human and financial resources to the most pressing issues – preventing the most injuries within the constraints imposed by a limited budget and limited time. Because cosmetics are on balance safer than drugs, foods, and medical devices, the FDA pays relatively little attention to cosmetics. Instead, the FDA confronts life-or-death issues such as AIDS, new life-saving drugs, and the threat of poisons in the nation's food supply. The FDA should not focus its attention and resources away from these problems unless by doing so the public health is significantly enhanced. Cosmetics in general, and AI{As in particular, are extremely unlikely to cause any serious, permanent injuries. Therefore, requiring the FDA to regulate cosmetics more stringently than it already does would be a mistake: its costs far outweigh any benefits.

In the final analysis, all of the issues in food and drug law require us to ask how much risk is acceptable in our society. The potential ability of AHAs to behave like drugs raises a serious question: does a statute written in 1938 adequately regulate the risks presented by the cosmetics products of the 1990s? Ultimately, we must accept that the Act protects us

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incompletely; some risks – such as those presented by AliAs –will remain exposed. Even though AliAs might cause some economic and physical injuries, however, the current regulatory environment adequately addresses the most serious problems that they present. Increasing regulation would cause only marginal reductions in risk, and at an unreasonable cost. Therefore, the current system governing cosmetics undoubtedly leaves risks, but they are risks that we can live with.

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1.21 U.S.C. §§ 301 - 395 (1988 & Supp. 1994)

2. Anti-aging creams, moisturizers and other facial products generate approximately \$2.5 billion each year for the cosmetics industry. See Judy Foreman, Skin Creams: The Help and the Hype, Boston Globe, November 9, 1992, at 29.

3. This paper focuses on the regulatory problems presented by alpha hydroxy acids and similar over-the-counter skin peeling agents. Consumers are also fighting wrinkles with the drug Retin-A, which physicians may prescribe for wrinkle reduction even though it has been approved only to treat acne. Plastic surgeons are also injecting wrinkled patients with collagen, a protein which has been approved by the FDA for wrinkle reduction. See Foreman, su~ra note 2, at 29.

4. See Leslie Laurence, Moisturizing Aloha Hydroxy Acids May Be the Next Anti-Aging Miracle, **Atlanta Constitution**, October 26, 1993, at D4; Robin Marantz Henning, It's A Cream. It's A Drug. It's A Cosmeceutical, **Wash. Post**, June 12, 1990, at Z10.

5. See Henning, su~ra note 4, at Z10.

6. See *id.*

7. See Jennifer Mann Fuller, Face Creams Provoke Debate, **Kansas City Star**, Sept. 18, 1994, at F4.

8. See 21 U.S.C. § 355 (1988 & Supp. 1994) (rigorous requirements for new drugs)

9. See 21 U.S.C. §§ 351, 361 (1988 & Supp. 1994) (adulteration),

id. §§ 352, 362 (misbranding). To avoid being misbranded, a cosmetic must bear a label with the name and place of business of the manufacturer, packer, or distributor and with a listing of the contents. See id. § 362(b).

10. See liening, su~ra note 4, at Z10 (quoting Avon Momentum label, which prompted FDA to act). As a result of FDA regulatory letters, Avon changed its label – mentioning only the product’s sunscreen protection (because Avon Momentum was already regulated as an over-the-counter sunscreen drug) . See id.

11. Ironically, if research proves that AliAs really work, manufacturers will still refrain from describing how they work in order to avoid the drug approval process. Thus, consumers might be deprived of information from manufacturers about the effectiveness of AliAs.

12. See Peter Barton Hutt, Reconciling the Legal. Medical. and Cosmetic Chemist ADproach to the De
3 CTFA Cosmetic Journal, No. 3 (1971), reDrinted in Peter Barton Hutt
& Richard A. Merrill, Food and Drug Law 824 (2d. ed. 1991).

The FDA has also listed a small number of substances that will cause a product to be classified as a drug regardless of the claims made about the product. See 42 Fed. Reg. 56757 (October 28, 1977)

13. 21 U.S.C. § 321(i) (1988 & Supp. 1994).

14. 21 U.S.C. § 321 (g) (1) (1988 & Supp. 1994) . The clause defining drugs specifically excludes any food that is intended to affect the structure or any function of the body. ~

15. See Hutt, su~ra note 10, at 824.

The drug definition also includes articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary

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. 21 U.S.C. § 321(g) (1) (A) (1988 & Supp. 1994). If this language was taken literally, then virtually all cosmetics would be drugs. This is the rationale for focusing on a product's intended use. See Samia Nahir Rodriguez, Cosmetic or Drug? The Minotaur's Labyrinth Revisited, 44 **Food Drug & Cosmetic L.J.** 63, 79 (1989)

16.A drug claim would constitute any representation that a product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or that a product will affect the structure or any function of the body. See Rodriguez, su~ra note 15, at 64 - 65.

17.See Hutt, su~ra note 12, at 825. When necessary to effectuate the purposes of the Act, the FDA has applied a broad interpretation of when a manufacturer makes an improper drug claim. For example, the inclusion of the word hormone in cosmetic labeling constitutes an implied drug claim, even though a manufacturer with the same product may use the hormone's chemical name. See 54 Fed. Reg. 40618 (October 2, 1989)

18.See 42 Fed. Reg. 56757 (October 28, 1977).

19.See 21 U.S.C. § 355 (1988 & Supp. 1994) (OTC drug requirements)

20.409 F.2d 734 (2d Cir. 1969), rev'g 288 F.Supp. 29 (E.D.N.Y. 1968)

21.Id. at **739**.

22.Id. at 740.

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23. See id. at 741 - 42.

24. 415 F.2d 369 (3d Cir. 1969)

25. See id. at 372.

26. Id.

27. 331 F.Supp. 912 (D.Md. 1971)

28. Id. at 917.

29. See Emalee G. Murphy, Cosmeceuticals - The Regulatory Environment or the Cosmetic Wars and Other Phenomena, 44 Food & Drug L.J. 41, 43 - 44 (1989) (describing letters from Daniel L. Michels, Director, Office of Compliance, Center for Drugs and Biologics, to various skin care companies (1987))

30. See Murphy, supra note 29, at 44 (quoting regulatory letters from John M. Taylor, Associate Commissioner for Regulatory Affairs, to cosmetic skin care companies (Nov. 19, 1987))

31. See id.

32. See Hening, supra note 4, at ZIO. Estee Lauder sought a declaratory judgment that the FDA'S position as unlawful, unreasonable, arbitrary, and capricious, but its suit was dismissed for lack of ripeness. See Estee Lauder v. United States Food & Drug Administration, 727 F.Supp. 1 (D.D.C. 1989).

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33. See Rodriguez, supra note 15, at 74 (quoting transcript of Frank. E. Young, Commissioner of Food and Drugs, FDA, at the Second International Conference on Cosmetic Regulation, Washington, D.C., at 7 (April 25, 1988)).

34. An exception to this rule is that the FDA has listed sixteen substances that are generally recognized as drugs and are not known to be used as cosmetic ingredients regardless of the claims made for them.

35. However, if a manufacturer uses a biologically active ingredient at concentration described in an over-the-counter drug monograph, the FDA may require the cosmetic product to comply with the monograph. An example of this is the use of sunscreen agents in cosmetics. Even if the manufacturer does not make drug claims (i.e., by listing the sun protection factor or by making sunscreen claims), the product must comply with OTC regulations if the sunscreen is listed as an active ingredient. See FDA Compliance Program Guidance Manual 7329.001 (November 19, 1988), cited in Hutt & Merrill, supra note 12, at 830 - 31.

36. See 21 U.S.C. § 361 (1988 & Supp. 1994)

37. See, e.g., *United States v. An Article of Cosmetic . Beacon Castile Shampoo ..*, (N.D. Ohio 1974) (reprinted in Hutt & **Merrill**, supra note 12, at 831 - 32) (requiring evidence of injury to be objectively and medically demonstrable that [the cosmetic] is damaging either externally or internally and noting that pain alone without objective injury would not be enough)

38. Under rulemaking proceedings, the FDA has banned very few ingredients from cosmetic products. See GAO Report (1978), reprinted in **Hutt & Merrill**, supra note 12, at 821.

39. See id. at 820.

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40. See Martin Tolchin, Are Cosmetics Safe? Study Raises Questions, **Minneapolis Star Tribune**, May 6, 1990, at 1E.

41. See id.

42. See Fuller, *supra* note 7, at F4 (reporting that FDA received only two dozen complaints of temporary adverse reactions to AHAs in all of 1993)

43. See Diana Greenfield, Beyond Cosmetics: The FDA Considers Aloha Hydroxy Acids, **Neweday**, October 13, 1994, at B22. The Cosmetics Ingredient Review Board consists of independent dermatologists plus non-voting representatives from the FDA and the Cosmetics, Toiletries, Fragrance Association.

44. See 21 U.S.C. § 602 (1988 & Supp. 1994)

45. 21 U.S.C. § 362(a) (1988 & Supp. 1994).

46. See 16 C.F.R. § 1500.81(a).

47. See 21 C.F.R. § 740.10 (1994)

48. Wrinkle creams sold over the counter today have AHA concentrations ranging from less than 1 percent to about 15 percent. ~ Foreman, *supra* note 2, at 29.

49. See 40 Fed. Reg. 8912 (March 3, 1975).

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50. See Hening, supra note 4, at Z1O.

51. See Tolchin, supra note 40, at 1E.

52. See id.